Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of	)	
	)	
Request by Nalu Medical, Inc.	)	
For Waiver of Section 15.229	)	File No. _____
of the Commission's Rules	)	

To: Chief, Office of Engineering and Technology

REQUEST FOR WAIVER

Nalu Medical, Inc. ("Nalu"), pursuant to Section 1.3 of the Federal Communications Commission's ("FCC" or "Commission") rules,[1] hereby requests a waiver of Section 15.229[2] of the rules to obtain equipment certification for a dual-mode Part 15/Part 18 implantable medical device. The Nalu System sends both power and data from the same transmitter, allowing for innovative, minimally invasive medical implants. Grant of this request would be consistent with the intent of the rule, and would be in the public interest as it would allow the marketing of medical devices that would improve patient outcomes, at a much lower cost than current medical therapies and other medical devices presently on the market.

BACKGROUND

Nalu is a medical device start-up, headquartered in Carlsbad, California. It is presently developing the Nalu System, which will be a FDA-regulated wireless medical device, to be submitted to the FDA for clearance. While the Nalu System will be Nalu's first product, the Nalu

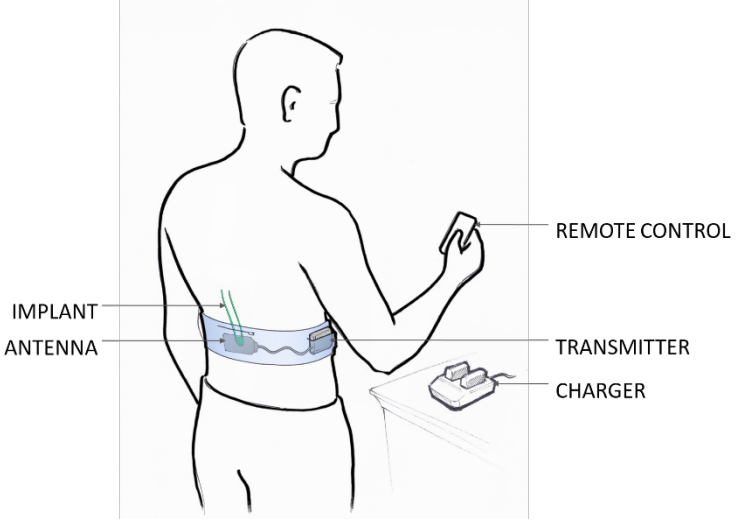
[1] 47 C.F.R. § 1.3.

[2] 47 C.F.R. § 15.229 (incorporating Section 15.209 out-of-band field strength emission requirements for operations within the 40.66-40.70 MHz band).

team is composed of experienced medical device industry business leaders and engineers who are well-versed in designing novel and effective medical devices.

About the Nalu System

The Nalu System consists of a miniature passive implant (termed an Implanted Neural Stimulator, or INS) that is powered from an externally worn device (termed an External Transmitter Module, or ETM). The ETM houses the electronics for the RF link, controller/programmer communication systems, and battery management, and drives the antenna module that powers and communicates with the INS. The power source for the ETM will be a rechargeable battery. The ETM is worn by the patient. The patient may also be provided a remote control system, utilizing Bluetooth Low Energy, to manipulate the device settings. An example use case for the treatment of back pain is shown below:



The Nalu System will use various waveforms to provide nerve stimulation for pain relief and other therapy. One use will be stimulation of the spinal cord to treat chronic lower back and limb pain; other medical uses include stimulation of the sacral nerves to treat overactive bladder conditions, stimulation of the tibial nerve to treat diabetic neuropathy and stimulation of peripheral nerves to treat various peripheral pain conditions.

There is no commercially available, active implanted device for tibial nerve stimulation in the United States. There are spinal cord and sacral root stimulation devices currently on the market that provide similar medical treatment, but they have significant drawbacks that the Nalu System is designed to address:

- The Nalu implant is substantially smaller than devices currently on the market, approximately the size of a dime, while others are much larger than a stack of quarters.[3] This small size will enable the Nalu implant to be placed in the patient through a minimally invasive surgical procedure.[4] In contrast, the much larger devices on the market require insertion through a much larger incision, and these procedures often result in post-surgical pain, discomfort and other complications for the patient.[5]

- Placement of the Nalu implant will require much less surgical time. Nalu estimates that placement of its implant will take 15 minutes of surgery, as compared to 60 minutes for devices currently on the market. Reduced surgical time will save substantial amounts of money for hospitals and surgical centers where the implants will be performed. Physicians also cab treat more patients per day by spending less time in surgery, and it is safer for patients to spend less time under anesthesia.

- The Nalu implant is externally-powered,[6] allowing it to remain in use for an estimated lifetime of 15-20 years. Currently available devices are battery-powered and thus require replacement surgery every 3-7 years, which is painful and costly. Nalu estimates that, over a 10 year period, treatment with the Nalu System will generate a significant savings in health care costs, estimated at $100,000 *per patient*.[7]

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[3] The Nalu implant is approximately 20-40 times smaller in volume than devices currently on the market.

[4] Implants are inserted into a patient by creating a subcutaneous channel followed by insertion of the implant through the channel to the desired position within the patient.

[5] Approximately 5-10 % of patients who are treated with implantable pulse generators experience significant pain post-surgery. *See* Timothy Deer, M.D. *et al.*, "Results from the Partnership for Advancement of Neuromodulation Registry: A 24-Month Follow-Up," 19 NEUROMODULATION: TECH. AT THE NEURAL INTERFACE 179 (2016).

[6] The system uses load modulation for reverse telemetry (implant to external).

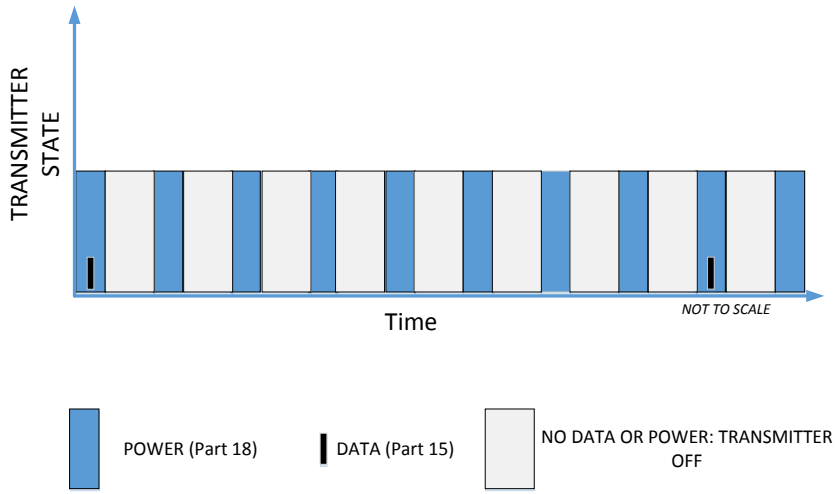
[7] *See* John Hornberger *et al.*, 24(3) *Rechargeable Spinal Cord Stimulation Versus Non-Rechargeable System for Patients with Failed Back Surgery Syndrome: A Cost-Consequences Analysis*, CLINICAL J. PAIN, 244 (2008), *available at* https://www.ncbi.nlm.nih.gov/pubmed/18287831 (finding that rechargeable spinal cord

- The Nalu System addresses two types of system failures that occur in 2.5% of patients – premature battery failure and pain over the implant site.[8]

Depending on therapeutic need, a clinician will program the ETM to set the stimulation regime, and some patients may wear the ETM for up to 24 hours per day.

Nalu System RF Characteristics

The Nalu System will engage in both Part 18 and Part 15 operations. Part 18 emissions will be used to power the implant, while Part 15 will be used, much less frequently, to send small amounts of data to program the implant, to confirm that the implant is functioning correctly and to query the power supply condition. Both power and data communications are sent from the external device (the ETM); because the system uses "load modulation" for return communications, the implant does not need a separate transmitter. A graphical representation of the transmissions is shown below (not to scale):



stimulation systems have a savings of $104,000-$168,833 over non-rechargeable systems that must be replaced every 2-5 years).

[8] *See* Tracy Cameron, PhD., *Safety and Efficacy of Spinal Cord Stimulation for the Treatment of Chronic Pain: a 20-year Literature Review*, 100(3 Suppl. Spine) J. OF NEUROSURGERY 254 (2004).

Power and communications will both transmit on the 40.68 MHz ISM frequency, selected to maximize communication efficiency while minimizing tissue absorption loss. Because other frequencies do not propagate as well inside the body, 40.68 MHz is the best frequency for this type of device as it allows for medically satisfactory communications with a miniaturized implant. Use of other bands would require a much larger implant, which would undermine the many benefits of the Nalu System.

Miniaturization requires that both the Part 18 and Part 15 transmissions be sent from the same transmitter. While the emissions are compliant with the Part 18 and Part 15 rules when transmitted individually,[9] and would be compliant if transmitted from two separate transmitters contained in the same implant, the Nalu System is not compliant with Part 15 emission requirements during limited periods of time when both data and power are transmitted simultaneously, as the Part 18 emissions cause the device to exceed the Part 15 limit.[10]

The Nalu System will enable simplified surgery for the patient, will reduce health care costs significantly, and will lower or eliminate post-surgical pain and complications.

DISCUSSION

Nalu seeks waiver of the power limit in Section 15.229. Waiver should be granted because the underlying purpose would not be served by application of the rule – no useful purpose will be served by requiring power transfer and communications functions to be done on separate frequencies. The benefits of the implant in providing medical treatment to those with

[9] There is no in-band power limit for Part 18 ISM operation, and the Nalu System's out-of-band emissions comply with the Part 18 out-of-band limits in Section 18.305(b). Communications emissions comply with the Section 15.229 limits.

[10] This will happen less than 5% of the time, as the data duty cycle is less than 5%.

back pain and other disorders, without any realistic risk of interference to other users, are plainly within the public interest.

A. Request for Waiver.

The Nalu System requires both Part 15 and Part 18 equipment approval. The Nalu System would be 100% compliant with FCC rules, and not require a waiver, if it could be designed with two RF chips, one for power and one for data transmission. In that instance, the total emitted signal strength would be allowable. However, here miniaturization requires the use of just one chip. When both power and communications data are transmitted, which would occur less than 5% of the time, the combined emissions exceed Part 15 limits.

Nalu's request is similar to one granted to EnteroMedics, though in that instance the dual-mode medical device operated on the 6.78 MHz ISM frequency band.[11] In granting the waiver to EnteroMedics, the Office of Engineering and Technology determined that:

> [W]e recognize that the medical implant components of these devices are designed to operate optimally and less intrusively by performing the communication and power transfer functions at a single frequency, and we conclude that no useful purpose would be served by requiring that these functions be performed on separate frequencies for this type of device.[12]

The same reasoning applies here. No useful purpose would be served by requiring Nalu to design its system with two chips, something that would only undermine the many benefits of the Nalu System.

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[11] Letter from Julius P. Knapp, Chief, Office of Engineering and Technology, to Mitchell Lazarus, Counsel for EnteroMedics, Inc., DA 09-2425 (Nov. 20, 2009) ("*EnteroMedics Waiver*").

[12] *EnteroMedics Waiver* at 4.

B. Public Interest.

Grant of the waiver serves the public interest because it will allow for certification of a system that can provide the same patient benefits with fewer complications and at a much reduced cost. The Nalu System provides the following patient benefits: clinically proven therapy for pain relief or relief from symptoms of over active bladder. The Nalu therapy is equivalent to current devices on the market without the described drawbacks; minimally invasive surgery; fewer replacement surgeries; reduced device failure rates; and likely no pain or complications associated with implant site. The Nalu System also provides significant healthcare system benefits, such as reduced surgical time and cost, and significantly reduced long term cost of care, in the range of at least $100,000 per patient.

While the Nalu System could be designed to be rule-compliant, doing so would require sending power and communications through different transmitters. This would require an additional chip, antenna and circuitry, which would result in a larger device, one that could not provide the public interest benefits stated above.

The other allocations in the 40.68 MHz band are for Federal fixed and mobile radiocommunications and Part 90 Private Land Mobile communications.[13] These users must accept harmful interference from ISM applications. [14] The requested waiver will not increase the interference that they receive, given the very limited range of the Nalu System (no more than five centimeters), the much lower power level (~330 mW vs. tens or hundreds of watts employed by the seven licensees found in ULS), and the effects of body absorption.

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[13] 47 C.F.R. § 2.106. There is also secondary use allocated for Federal and non-Federal tracking of ocean buoys and wildlife.

[14] *Id.*; *see also* 47 C.F.R. § 90.20(73).

C. Legal Basis.

The Commission assesses waiver requests according to the standards set out in *WAIT Radio v. FCC*.[15] In that case, as here, the applicant sought authority in contravention of the rules while explaining how it would nonetheless accomplish the purpose of the rules.[16] The court required the Commission to consider the request:

> [A] general rule, deemed valid because its overall objectives are in the public interest, may not be in the "public interest" if extended to an applicant who proposes a new service that will not undermine the policy, served by the rule, that has been adjudged in the public interest.[17]

WAIT Radio is clear: waiver is appropriate where the applicant furthers the public interest inherent in the underlying rules.

The waiver requested here meets the *WAIT Radio* standard: it would allow for certification of a device that will advance the policy served by the rules. The Part 15 rules are designed to ensure that "there is a low probability that these unlicensed devices will cause harmful interference to authorized users."[18] Here, because the emissions are the same as a device that uses two compliant chips for the Part 18 and Part 15 operations, allowing certification would not impose any higher risk of interference than a compliant device. The requested waiver fits easily into the boundaries drawn by *WAIT Radio*.

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15 *WAIT Radio v. FCC*, 418 F.2d 1153 (D.C. Cir. 1969). *See also, 2002 Biennial Regulatory Review*, 18 FCC Rcd 13620 para. 85 n.130 (2003) (citing *WAIT Radio* as "setting out criteria for waivers of Commission rules.")

16 WAIT Radio operated an AM broadcast station. It was limited to daylight hours so as to afford protection to "white areas" that had no local service, and that relied on nighttime skywave propagation from another station. WAIT Radio proposed to transmit at night using a directional antenna that would limit its signal in the white areas. *WAIT Radio v. FCC*, 418 F.2d at 1154-55.

17 *Id*. at 1157.

18 *See Multispectral Solutions, Inc. Request for Waiver of Section 15.250 of the Commission's Rules*, Order, 22 FCC Rcd 9831 (2007).

The Court of Appeals emphasized the importance of waiver procedures as part of the regulatory scheme:

> The agency's discretion to proceed in difficult areas through general rules is intimately linked to the existence of a safety valve procedure for consideration of an application for exemption based on special circumstances.[19]

Thus, it said, "allegations such as those made by petitioners, stated with clarity and accompanied by supporting data … must be given a 'hard look."[20] Here, too, the request fully qualifies. The "safety valve" of the waiver procedure is needed to make available a device not otherwise available. The requested waiver is in the public interest, not only in terms of benefits to the public, but also in the absence of any downside. The request is entitled not only to the "hard look" mandated in *WAIT Radio,* but to a grant of the waiver.

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19 *418 F.2d at 1157.*

20 *Id.* (citation footnote omitted).

CONCLUSION

For the foregoing reasons, Nalu respectfully requests that the Office of Engineering and Technology grant waiver of the rules so that Nalu may obtain equipment certification for the Nalu System. Waiver is clearly in the public interest: benefits to patients and our healthcare system have the potential to be enormous, and the likelihood of increased harmful interference exceedingly minimal.

Respectfully submitted,

Nalu Medical, Inc.

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